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(54)	ORALLY DISINTEGRABLE TABLETS					
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(56)		R	eferences Cited			
U.S. PATENT DOCUMENTS						

5,433,959 * 7/1995 Makino et al. 424/475

5,501,861 * 3/1996 Makino et al. 424/464

FOREIGN PATENT DOCUMENTS

0446961		9/1991	(EP) .
761 212 A2	*	9/1996	(EP) .
0761212		3/1997	(EP) .
0799616		10/1997	(EP) .
WO 87/02240		4/1987	(WO).
WO 96/01624		1/1996	(WO).
WO 96/24375		8/1996	(WO).
WO 07/25066		7/1007	(WO)

^{*} cited by examiner

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(57) ABSTRACT

An orally disintegrable tablet, of the present invention, which comprises (i) fine granules having an average particle diameter of $400~\mu m$ or less, which fine granules comprise a composition coated by an enteric coating layer, said composition having 10 weight % or more of an acid-labile physiologically active substance and (ii) an additive, has superior disintegrability or dissolution in the oral cavity so that it can be used for treatment or prevention of various diseases, as an orally disintegrable tablet capable of being administered to the aged or children and easily administered without water. Also, because the tablet of the present invention contains fine granules having the average particle diameter such that it will not impart roughness in mouth, it can be administered easily without discomfort at the administration.

45 Claims, No Drawings